

● PRINTER RUSH ●
(PTO ASSISTANCE)

Application :	09/524,747	Examiner :	Wilson
From:	CWC	GAU :	1623
Location:	(IDC) FMF FDC		
Date:	04/28/05		
Tracking #: <u>ppm 09/524,747</u> Week Date: <u>04/04/05</u>			

DOC CODE	DOC DATE	MISCELLANEOUS
<input type="checkbox"/> 1449	_____	<input checked="" type="checkbox"/> Continuing Data
<input type="checkbox"/> IDS	_____	<input type="checkbox"/> Foreign Priority
<input type="checkbox"/> CLM	_____	<input type="checkbox"/> Document Legibility
<input type="checkbox"/> IIFW	_____	<input type="checkbox"/> Fees
<input type="checkbox"/> SRFW	_____	<input checked="" type="checkbox"/> Other
<input type="checkbox"/> DRW	_____	
<input type="checkbox"/> OATH	_____	
<input type="checkbox"/> 312	_____	
<input type="checkbox"/> SPEC	_____	

[RUSH] MESSAGE:

- 1) There is no brief description of drawings.
- 2) Continuing data on palm sheet is not in specification.

Thank you

[XRUSH] RESPONSE:

1. FIGS. in this chemical application are described on p. 9. This is sufficient.

2. Done. See instruction for cont. data entry on TRNA of 3-14-00.

INITIALS: JBH

NOTE: This form will be included as part of the official USPTO record, with the Response document coded as XRUSH.

REV 10/04

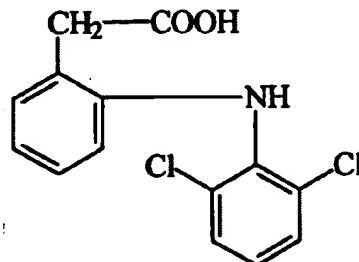
SBH
5-4-05

This application is a continuation-in-part of application Ser. No. 09/192493, filed 11-17-98, which is a continuation of PCT/EP97/02709, filed 5-15-97.

Pharmaceutical compositions based on Diclofenac

The present invention relates to new immediate release pharmaceutical compositions containing [(2,6-dichloro-anilino)-2-phenyl]-2-acetic acid (more commonly known as Diclofenac) in acid and/or salt form.

- 5 Diclofenac is a non-steroidal drug which was invented at the end of the sixties by A.Sallmann and R.Pfister (NL-6,604,752 and US-3,558,690 both to Ciba-Geigy) and whose structural formula is indicated below.



- 10 Diclofenac is widely dispensed and used owing to its well-known analgesic, anti-pyretic, anti-arthritis, anti-phlogistic and anti-rheumatic properties and it is generally taken orally in the form of normal tablets or tablets covered with coatings resistant to gastric juices, or rectally, or by injection, or topically.

- 15 The possibility of taking it in the form of sweets, tablets dissolving in the mouth, dragees, chewing gum or other similar pharmaceutical forms or in formulations for the extemporary preparation of Diclofenac-based aqueous solutions and/or suspensions would represent a different mode of administration which is definitely more suitable, especially for children and elderly persons.

- 20 Owing to its poor solubility in water, Diclofenac is normally used in salt form; the salts of Diclofenac customarily used are those of sodium, potassium or other alkali and alkaline earth metals, together with salts of organic nature, such as the salts of basic amino acids, such as lysine, arginine and ornithine, or other pharmacologically acceptable organic bases which have the ability to render the resulting salt soluble in water.

- 25 The pharmaceutical compositions of the Diclofenac salts for oral use are generally accompanied by side effects of not inconsiderable consequence: Diclofenac salts